

(19) World Intellectual Property Organization International Bureau

(43) International Publication Date
2 December 2004 (02.12.2004)

PCT

(10) International Publication Number
WO 2004/103350 A1(51) International Patent Classification⁷: A61K 9/50, 31/5585

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(21) International Application Number: PCT/IB2004/001912

(22) International Filing Date: 19 May 2004 (19.05.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data: 03291180.2 20 May 2003 (20.05.2003) EP

(71) Applicants (for all designated States except US): ETHY-PHARM [FR/FR]; 21, rue Saint-Mathieu, F-78550 Houdan (FR). TORAY INDUSTRIES, INC. [JP/JP]; 2-1, Nihonbashi, Muromachi 2-chome, Chuo-ku, Tokyo 103-8666 (JP).

(72) Inventors; and

(75) Inventors/Applicants (for US only): SALLE, Sandrine [FR/FR]; 4, route de Rosny, F-78980 Saint Illiers La Ville (FR). GUERIN, Emmanuel [FR/FR]; 4, rue Maurice Berteaux, F-92700 Colombes (FR).

(74) Agents: MARTIN, Jean-Jacques et al.; Cabinet Regimeau, 20, rue de Chazelles, F-75847 Paris Cedex 17 (FR).

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— of inventorship (Rule 4.17(iv)) for US only

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2004/103350 A1

(54) Title: ORAL SUSTAINED RELEASE PHARMACEUTICAL COMPOSITION

(57) Abstract: An oral sustained release pharmaceutical composition comprising a plurality of granules having diameters of not more than 1000 gm, each of which comprises a nucleus granule containing beraprost sodium, and a coating agent constituting at least two skin layers including (1) a skin layer containing a relatively water-insoluble macromolecular substance and (2) a skin layer containing a hot-melt low-melting substance, said nucleus granule being coated with said coating agent.